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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,690	06/30/2003	Jonathan Scott Darling	990892-30	7686
7590 02/07/2007 Brown, Winick, Graves, Gross, Baskerville and Schoenebaum, PLC Camille L. Urban 4500 Westown Parkway - Suite 277 West Des Moines, IA 50266			EXAMINER STOICA, ELLY GERALD	
			ART UNIT 1647	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/07/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/607,690

Applicant(s)

DARLING ET AL.

Examiner

Elly-Gerald Stoica

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 17-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 17-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/30/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/16/2006 has been entered.

Specification

2. The disclosure is objected to because of the following informalities: the enzyme "keratinase" is misspelled as "keritinase".

Appropriate correction is required.

3. Claims 4, 17, 22 are objected to because of the following informalities: the enzyme "keratinase" is misspelled as "keritinase". Claim 3 contains the term "comprising" where the correct term is "comprises". In claims 4, 23, 24 and 25 a comma should be inserted before "wherein". Claim 9 has a "-" inserted between "for" and "recycling".

Appropriate correction is required.

Status of the claims

4. The amended claims 1-11 and 17-20 the new claims 21-25 are pending. The previous claims 12-16 are cancelled by the Applicant.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-11 and 17-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "enzymatic digest medium" in Claims 1 a, 1 b, 2, 4-5 and 10 renders those claims unclear as well as the dependent claims. The recitation "enzymatic digest medium" is unclear because the metes and bounds are not defined. Is this medium an enzyme in water or an enzyme in a buffer or an enzyme in any organic solvent or an enzyme that is dry or what? Is the enzyme added extraneously or contained in the fluid waste? Is the enzyme digesting fat, protein, carbohydrates or what? Appropriate correction/definition in the claim language regarding "enzymatic digest medium" is required.

In both part a) and part b) of claim 1 the phrase waste is present. It is unclear if the waste recited in part a) is ground in part b) of the claim. Also, in part d) of claim 1 the recitation "recirculation" lacks antecedent bases since no "circulation" was presented up to that particular point.

In claims 2, 4, 10, 22, and 25 the recitation "one preservative" is indefinite since it is not clear what is the subject matter that is supposed to be preserved.

Claims 4, 22 and 23 offers a description of the enzymatic digestive medium lacking the fat recited in the description of the medium in claim 1. Is this a new enzymatic digestive medium, different from the one described in claim 1?

Claims 4, 17 and 23 are indefinite because they contain the phrase "at least one enzyme wherein said at least one enzyme comprises protease and keritinase". **One** enzyme cannot comprise protease **and** keratinase.

Claim 8 is indefinite because the terms "heat zone" and "cool zone" are relative terms and one cannot establish the metes and bounds of the claim. Also is the recitation "alternative air flow" in claims 8, 11, and 25 referring to alternating between ON and OFF, or between hot and cold or something else?

Claim 20 recites the "high surface area to volume" property of the carrier without adequately describing its metes and bounds.

Claim 1 and 22 recites the limitation "said dough like mixture" in the sub numbering h). There is insufficient antecedent basis for this limitation in the claim.

As it was already mentioned in the Final rejection of 7/17/2006, the Applicant is reminded that the invention is the subject matter defined by the claims, and the limitations of the specification, clearly defined as they may be, are not read into the claims where no express statement of that limitation is provided/included in the claims (See, In re Priest, 199 USPQ 11). The Applicant is also made aware that the limitations appearing in the specification will not be read into the claims, and interpreting what is

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meant by word/phrase in a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper. (*Intervet Am., v. Kee-Vet Labs.*, 12 USPQ 2nd 1474, 1476 (Fed. Cir. 1989)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-11 and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (US Pat. 4,473,589) in view of Anderson et al. (US Pat. 5,053, 234) and in further view of Erickson (US Pat. 4,041,182) and Moss et al. (US Pat. 3,692,538).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Freeman et al. teach a method of obtaining a liquid product in a metabolically useful form from protein waste products. A preliminary mechanical breakdown of the protein source, such as by coarse grinding, and mixing facilitated the enzymatic

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reaction. The primary end product sought was a liquefied protein, lipid and phosphorous solution or emulsion. The process was particularly applicable to beef, pork, sheep, chickens and other large volume animal tissue. Typical source starting materials for the present process were poultry wastes of all types, including blood, internal organs, feathers, beaks, heads, and feet, whole birds (DOA's) and eggs. The amount of enzyme used in the enzyme hydrolysis step was about 0.1-1.0 weight percent of the weight of the starting protein source. In one of the embodiments, the enzymatic digestion was executed at temperatures between 100-140 ° F. It well known in the art that the temperature for enzymatic digestions is to kept within this range so as to increase the speed of the enzymatic process without denaturing the enzymes. Optimal results were obtained wherein preservation is accomplished by adjusting the pH of the hydrolysate of the second stage with a suitable mineral acid such as phosphoric acid to less than about 4.2, meeting the claim limitations of between 4 and 6 (col 3 lines 50-54, 68-69 and col. 4, lines 14-27, also claims 12-14). Poultry wastes of all types, including blood, internal organs, feathers, beaks, heads, and feet, whole birds (DOA's) and eggs can be used in this method (e.g. chicken feathers, col 4, lines 51-53 and Example III). The method produced almost complete liquefaction with a solution which was well preserved on the acid side (Example VIII). The teachings of Freeman et al. meet the limitations of the claims with regard to the starting and the intermediary products, as well as for the enzymatic digestion. Freeman et al. is silent about the nature of the end product or about the method of emulsifying the enzymatic solution.

Analog to Freeman et al., Anderson et al. teach a method of making a particulate proteinaceous product from waste raw protein-containing animal parts with a method and an apparatus having a milling stage wherein the raw animal parts are reduced to a ground condition; a hydrolyzing stage wherein proteins in the ground animal parts are hydrolyzed to a predetermined extent to form an aqueous suspension, using either endogenous or supplementary proteolytic enzymes, and subsequently heated to inactivate the enzymes and convert fats in the suspension to oils; a concentration stage wherein extraneous oil is added to the suspension. A portion of the removed oil is routed back to the beginning of the concentration stage as extraneous oil added to the suspension to permit sufficient water to be removed from the suspension without forming a stiff, unprocessable mass, which would clog the equipment. The method is distinctive in that it produces a dry product, compressible into pellets or cakes as an end product, similar to the claims in the instant application (abstract Claims 1,3, 4, 26, and 28).

Erickson et al. teach a method for manufacturing a bioprotein animal feed supplement comprising: providing a slurry of raw organic waste containing biochemically volatile and biochemically non-volatile components, converting said biochemically volatile component to water soluble lower molecular weight intermediates essentially by the addition of organism-free hydrolyzing enzymes to said raw organic waste slurry at a temperature of about 100-120 ° F. The method comprises the mixing and emulsifying the solution of fats and oils. (col 3, lines 66-col 4 Line 55, and claim 1 and 3).

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Moss et al. present the general state of the art in protein waste recycling by teaching the method to obtain a product for animal nutrition using starting material of inedible quality (col. 2 lines 1-5 and 13-16)

The art, at the time of the invention was made, as exemplified above was well aware of the methods of recycling the protein waste of various sources. It would have been obvious to envision a method to process that would use the enzymatic process suggested by Freeman carried out at the appropriate temperatures and pH as taught by Erickson and to employ the teaching of Anderson to obtain first a product that is in liquid form and not prone to clogging of the equipment and finally a dry product that would have been easier to be transported and handled, with a reasonable expectation of success. The motivation for such an approach is offered by Moss et al., which underscores the need of recycling protein waste for animal nutrition.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-11, 17-25 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 4, 6, 8, 13, 15, 16, 18, 20, 21, and 22 of copending Application No. 10607691. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is claiming the apparatus to perform the method with and the steps of the methods are recited partially in the before mentioned claims of the copending Application No. 10607691. It is noted that no restrictions between the respective inventions has been required in either case.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elly-Gerald Stoica whose telephone number is (571) 272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER